4. 510(k) Summary

Prepared June 18, 2002

TRADE NAME **GENERIC NAME** **CLASSIFICATION**	Titan™ Micro Catheter and accessory HD Injector Catheter, Continuous Flush and Syringe Class II (21 CFR 870.1210) and Class II 21 CFR870.4450
SUBMITTED BY	Micro Therapeutics, Inc. 2 Goodyear Irvine, CA 92618 **CONTACT** Bill Hyatt Regulatory Affairs (949) 837-3700
PREDICATE DEVICE(S)	MTI Rebar™ Micro Catheter (K993672) MTI Cadence Precision Injector (K011535)
DEVICE DESCRIPTION	The MTI Titan™ Micro Catheter is an end-hole, single-lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The catheter has a semi-rigid proximal shaft which transitions into the flexible distal shaft to facilitate the advancement of the catheter in the anatomy. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the catheter is coated to increase lubricity. The catheter is provided with a removable adapter for attachment to either standard luer fitting devices or the MTI HD Injector. The HD Injector is a 1 mL syringe with threaded plunger and a vial septum-piercing needle. The connector at the distal end of the injector is threaded for connecting to the MTI Titan™ Micro Catheter.
INDICATIONS FOR USE	The Titan Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy. The MTI HD Injector is intended for the infusion of physician-specified fluids with the MTI Titan™ Micro Catheter
TESTING	*In-vitro* performance testing of the MTI Titan™ Micro Catheter included dimensional inspection, tensile strength tests, burst pressure tests, flow rate tests, torque tests and performance under simulated conditions. The accessory MTI HD Injector underwent *in-vitro* performance testing including dimensional inspection, injection rate, thread engagement, clip movement, needle detachment, integrity of attachment to Titan Micro Catheter, fit of piston in barrel and leakage. The biocompatibility of the MTI Titan™ Micro Catheter and accessory MTI HD Injector was verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices. Test results confirmed biocompatibility of the catheter and injector when tested as an external communicating, blood contact, limited exposure (<24 hrs) device.
SUMMARY OF SUBSTANTIAL EQUIVALENCE	The MTI Titan™ Micro Catheter and the accessory HD Injector are substantially equivalent to the predicate devices in intended use and principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2002

Micro Therapeutics, Inc.
c/o Mr. Bill Hyatt
2 Goodyear
Irvine, CA 92618

Re: K022003
MTI Titan™ Micro Catheter
MTI HD Injector
Regulation Number: 870.1340, 870.1650
Regulation Name: Catheter Introducer, Angiographic Injector and Syringe
Regulatory Class: Class II (two)
Product Code: DYB, DQF
Dated: June 18, 2002
Received: June 19, 2002

Dear Mr. Hyatt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K022003

6. Indications for Use Statement

510(k) Number (if known): _____

Device Name: MTI Titan™ Micro Catheter
MTI HD Injector

Indications for Use: The Titan Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.

The MTI HD Injector is intended for the infusion of physician-specified fluids with the MTI Titan™ Micro Catheter.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over the Counter Use** _____
(Per 21 CFR 801.109)

Division of Cardiovascular & Respir...
510(k) Number K022003